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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,305	01/14/2005	Toru Ishibashi	1232-5579	9351
27123 7590 05/18/2007 MORGAN & FINNEGAN, L.L.P. 3 WORLD FINANCIAL CENTER NEW YORK, NY 10281-2101			EXAMINER BHAT, NARAYAN KAMESHWAR	
			ART UNIT 1634	PAPER NUMBER
			MAIL DATE 05/18/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/521,305	<b>Applicant(s)</b> ISHIBASHI ET AL.	
	<b>Examiner</b> Narayan K. Bhat	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                                                               |                                                                                         |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                                          | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/14/2005; 4/11/2006 &amp; 6/12/2006</u> . | 6) <input type="checkbox"/> Other: _____                                                |

**DETAILED ACTION**

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed on January 14, 2005. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

**Election/Restrictions**

2. Applicant's election without traverse of group V invention in the reply filed on March 13, 2007 is acknowledged.

4. Claims 1-23 are pending in the application.

5. Claims 1-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on March 13, 2007.

6. Claims 14-23 are under prosecution.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 21-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 21, the claim recites, "second functional group" in line 2 and is confusing because there are two "second functional group" recitations in the claims (claim 1 and 21).

9. Claim 22 is indefinite because it depends on claim 21.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 14-17 and 19-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Chrisey et al (USPN 5,688,642 issued November 18, 1997).

Regarding claim 14, Chrisey et al teaches a method of immobilizing a probe to a solid phase carrier that include glass with hydroxylated surface (Fig. 1, element # 12, Column 7, lines 33) providing a DNA oligomer having thiol group, i.e., mercapto group (Fig. 3, See top panel- DNA oligomer with –SH group); providing an immobilized organosilane reagent having two reactive sites, one reactive site forming a covalent bond with the hydroxyl group on the glass substrate, thus immobilizing to the substrate,

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and the second reactive site available for binding to a molecule distinct from both substrate and other organosilane molecules ( Fig. 3, See bottom panel; Column 4, lines 19-33).

Chrisey et al further teaches that second reactive site has amino group that can form a covalent bond with the DNA molecules via reacting with succinimide ester group of the heterobifunctional cross linker SPMB (Column 8, lines 8-13) and therefore is the functional group. The second reactive site of organosilane having amino functional group capable of immobilizing to the substrate as taught by Chrisey et al is an immobilization substrate having a second functional group of the instant claim.

Chrisey et al further teaches that the DNA oligomer has a spacer of C3-C6 between the DNA and the mercapto group (Chrisey et al also refers nucleic acid molecules as NAM; Column 9, lines 54-61) thus teaching a linker between the DNA and the mercapto group. Chrisey et al also teaches that the thiol modified DNA can form a covalent bond with the amino group of the organosilane via reacting with maleimide group of the heterobifunctional cross linker SPMB (Column 8, lines 8-13) and therefore is the functional group. The mercapto group of the DNA oligomer having a linker as taught by Chrisey et al is the probe having a linker containing the first functional group of the instant claim.

Chrisey et al further teaches that the probe immobilization to the substrate by thiol modified DNA forming a covalent bond with maleimide group of the heterobifunctional cross linker SPMB and succinimide ester group of the heterobifunctional cross linker SPMB forming a covalent bond with the amino group of

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the organosilane (Column 8, lines 8-13), which is immobilized on the surface (See also Fig. 3, bottom right panel, SPMB is another heterobifunctional linker similar in function to the EDA listed in fig. 3). The mercapto and the amino group taught by Chrisey et al are also the acidic and basic functional group as defined in the instant specification (see instant specification, Paragraph 0036). Teachings of Chrisey et al thus encompass imparting the probe to the immobilization substrate; and binding the first functional group and the second functional group to each other, wherein a combination of the first functional group and the second functional group comprises an acidic functional group and a basic functional group.

Regarding claims 15 and 23, as described previously, Chrisey et al teaches first functional group, that is mercapto group and the second functional group that is the amino group. These inherently are acidic and basic groups as defined in the instant specification (see instant specification, Paragraph 0036). The dissociation constant of amino group is  $1.0 \times 10^{-6}$  (See the instant specification, Paragraph 0025) and the mercapto group is  $1.0 \times 10^{-12}$  or more and the dissociation constants are inherent properties of the functional groups that are chosen and both the groups of the instant claim are taught by Chrisey et al. Furthermore when the thiol group or the amino group binds to each other, causes a change in the properties that are inherent to the "thiol and amino groups" including the mutual chemical shift of signals in the NMR spectrum.

Regarding claims 16 and 17 Chrisey et al teaches that probe comprises of a DNA oligomer (Fig. 1, element # 19) and the spacer, i.e., linker is between the DNA and the thiol group (Column 9, lines 54-61) which is at the 3' terminal (Fig. 3, top panel; see the -thiol group at the 3' end of the DNA oligomer), thus linker is at the 3' end.

Regarding claims 19 and 20, as described previously, Chrisey et al teaches the thiol group, that is mercapto group as the first functional group and the primary amino group (-NH<sub>2</sub> group) as the second functional group (Fig. 3) and are the acidic and basic functional groups.

Regarding claim 21, Chrisey et al teaches that the probe immobilization to the substrate by thiol modified DNA forming a covalent bond with maleimide group of the heterobifunctional cross linker SPMB and succinimide ester group of the heterobifunctional cross linker SPMB forming a covalent bond with the amino group of the organosilane (Column 8, lines 8-13), which is immobilized on the surface (See also Fig. 3, bottom right panel). The maleimide group of the heterobifunctional cross linker SPMB taught by Chrisey et al is the "second functional group" of the probe thus teaching the probe has a second functional group introduced by treatment of the solid phase carrier with a silane coupling agent of the instant claim.

Regarding claim 22, Chrisey et al teaches the substrate is the glass (Column 7, lines 24-33), which is a solid phase carrier of the instant claim.

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chrisey et al (USPN 5,688,642 issued November 18, 1997) in view of McGovern et al (USPN 6,159,695 issued December 12, 2000).

Claim 18 is dependent on claim 14. Teachings of Chrisey et al regarding the claim 14 are described previously in this office action.

Regarding claim 18, Chrisey et al teaches immobilizing probe linker contains spacer molecules of C3-C6 (Column 9, lines 54-61). Chrisey et al do not teach the linker



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comprises a polyether chain. McGovern et al teaches attachment of tether linker to oligonucleotides (Fig. 4) with polyether linker of 2-50 unit (Column 22, lines 53 –58). McGovern et al also teaches tether linker supply the oligonucleotide with reactive functionality so that it can be chemically manipulated, and to allow the oligonucleotide to extend any specified distance away from the surface (Column 7, lines 18-22).

It would be obvious to one having the ordinary skill in the art at the time the invention was made to use the oligonucleotide with tether linker with polyether chain as taught by McGovern et al as an alternatives to the C3-C6 linker containing DNA oligomer of Chrisey et al. One would be motivated to do so to provide additional equivalent probes and also with the expected benefit of providing additional reactive functionality so that probe can be chemically manipulated, thus allowing the oligonucleotide to extend any specified distance away from the surface as taught by McGovern et al (Column 7, lines 18-22) thus improving the DNA sensor capabilities of Chrisey et al.

### ***Conclusion***

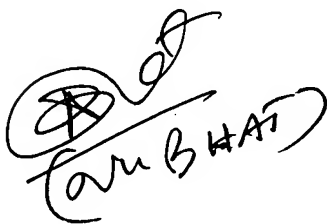
15. No claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Narayan K. Bhat whose telephone number is (571)-272-5540. The examiner can normally be reached on 8.30 am to 5 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla can be reached on (571)-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Narayan K. Bhat Ph. D.

Examiner

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**JULIET C. SWITZER**  
**PRIMARY EXAMINER**